

REMARKS

Amendments to the specification represent addition of information designating the depository, accession number, and deposit date of the deposited Huh-7.5 cell line in ATCC as per the requirements of 37 CFR 1.809(d). The insertion of such information in the specification after the filing date does not violate the prohibition against new matter in 35 U.S.C. §132 (see MPEP §2406.01, citing *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985)).

Claims 10, 12-15, 33-36, and 39-41 are currently pending. Claim 10 is currently amended.

SUMMARY OF JUNE 27, 2008 INTERVIEW

On June 27, 2008, the Applicant's representative conducted a telephonic interview with Examiner Zachariah Lucas to discuss proposed amendments to the specification and the related statement addressing deposit information and assurances of public availability of the deposit. Examiner indicated that the format of the amendment and statement as shown herein would satisfy the deposit information and public availability requirements if accompanied by the undersigned agent's signature.

CLAIM OBJECTIONS

The Examiner suggested that previously pending claim 10 be amended to indicate that the HCV RNA is capable of replicating rather than replicating. Applicants have amended claim 10 to recite "(a) providing an Huh-7.5 cell line on deposit with the ATCC as accession number

PTA-8561 that further comprises a ~~replicating~~ genomic or subgenomic HCV RNA capable of replication,” as per the Examiner’s suggestion.

CLAIM REJECTIONS

35 U.S.C. § 12, first paragraph – Enablement

The Examiner has raised new grounds for rejection of claims 10, 12-15, 33-36, and 39-41 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Examiner has rejected the claims as “relying on a Deposit without a promise for availability.” (Final Office Action dated May 1, 2008, page 5, second paragraph). As the Applicant’s agent, and having received signed assurances from the Applicants, the undersigned represents that the deposit with the ATCC of the Huh-7.5 cell line accorded the accession number PTA-8561 was made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent. As indicated by the Examiner, Applicant’s believe that the above statement by an agent of record over the agent’s signature satisfies in part the deposit requirements of 37 C.F.R. 1.808. (Final Office Action, page 5, last paragraph carrying over onto page 6).

The Examiner also alleges that the deposited cell line identified as ATCC deposit PTA-8561 is required to practice the claimed invention and therefore as a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. The Examiner instructs that if it is not

so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph may be satisfied by a deposit of the claimed/described cell line. The Examiner alleges however that Applicant's deposit statement in the abstract of the specification page does not indicate the extent of public availability. Applicants have currently amended the specification in compliance with 37 C.F.R. 1.809(d) so as to identify the accession number of the deposit, the date of deposit, a description of the deposited material, and the complete name and address of the depository. Applicants thus believe that the this amendment to the specification clearly indicates the public availability of the deposited cell line.

In view of the foregoing considerations Applicants respectfully request that the rejection of claims 10, 12-15, 33-36, and 39-41 under 35 U.S.C. §112, first paragraph be withdrawn.

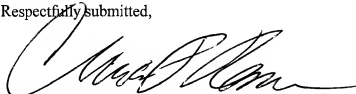
CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present Application is in condition for allowance. If the Examiner believes, for any reason, that a personal communication will expedite prosecution of this Application, he is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required beyond those which may otherwise be provided for in documents accompanying this Response. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such

extensions of time are hereby petitioned for under 37 C.F.R. §1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account 20-0823.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Charles P. Romano', written over a horizontal line.

Charles P. Romano, Ph.D., Reg. No. 56,991

Thompson Coburn LLP

One US Bank Plaza

St. Louis, MO 63101-1693

(314) 552-6255

(314) 552-7255 (fax)

Agent for Applicants

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